UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: RANBAXY GENERIC DRUG APPLICATION ANTITRUST LITIGATION	MDL No. 2878
THIS DOCUMENT RELATES TO: All Actions	Master File No. 19-md-02878-NMG

PURCHASERS' SUBMISSION CONCERNING
TRIAL DATE, LENGTH, AND TIME ALLOCATION

In response to this Court's request,[1] and consistent with the Court's remarks during the December 21, 2021 status conference, the purchasers and certified classes respectfully propose that the Court (1) set a roughly three-week trial (15 trial days, not counting empanelment or religious observance[2]), (2) calendar opening statements for March 1, 2022 and set deadlines for the remaining pretrial events, and (3) allocate more trial time to the plaintiffs. The purchasers suggest that 60% of the total trial time be allocated to the purchasers (directs and end payors collectively).

Trial date. The purchasers agree with the Court's initial suggestion that opening statements be set for March 1, 2022, with empanelment the day before. But, for clarity, we do not object to proceeding on April 5, 2022.[3]

[1] *See* ECF #530 (Clerk's notes indicating the Court would entertain short submissions from the parties of no more than 5 pages). The purchasers reached out to the defendants in an attempt to make a joint submission, but given divergent views on whether any submission was even requested by the Court, the parties were unable to reach agreement.

[2] Defense counsel confirmed that the only days off they are seeking for Passover (as requested at the Status Conference) are Friday, April 15 and Friday, April 22.

[3] The purchasers recognize that, on January 5, 2022, the District of Massachusetts suspended jury trials for the balance of the month of January in recognition of the current impacts of COVID-19 on our community's safety.

Regardless of whether the Court selects March 1 or April 5,[4] the purchasers believe that the pretrial timeframes previously set by the Court should govern. Those would result in the following pre-trial benchmarks (which, of course, can be adjusted as the Court sees fit):

Opening Statements	Jury Selection	Final Pre-Trial Conference	Jury instructions & *voir dire* filed	MIL oppositions filed[5]
Tuesday, March 1, 2022	Monday, February 28, 2022	Tuesday, February 8, 2022	Thursday, February 3, 2022	Wednesday, January 26, 2022
Tuesday, April 5, 2022	Monday, April 4, 2022	Tuesday, March 15, 2022	Thursday, March 10, 2022	Wednesday, March 2, 2022

Trial length. At the December 21, 2021 conference, this Court suggested that three weeks of full trial days might be sufficient. To be sure, this case is complex. The jury will be asked to hold Sun and Ranbaxy accountable for billions of dollars in overcharges flowing from a decade-long campaign to obtain first-to-file marketing exclusivities by hiding from the FDA what it admitted internally—that Ranbaxy was incapable of ensuring that drugs developed and manufactured at *any* of its Indian manufacturing facilities (including the Paonta Sahib, Dewas, Mohali and Toansa facilities proposed to be used in obtaining FDA approval for generic Diovan, Nexium, and Valcyte), were safe and effective. But the purchasers agree that three weeks of evidence and argument (15 days of roughly 5 hours a day) should suffice for the parties to present opening statements, marshal their evidence, and make closing arguments[6]—

[4] At the December 21st conference, there was brief discussion of Ranbaxy's Rule 23(f) Petition for Permission to Appeal End-Payor Plaintiffs' Class Certification Order impacting the trial date. The First Circuit Court of Appeals denied the petition on December 21, so it is no longer a possible impediment to trial. *In re Ranbaxy Generic Drug Application Antitrust Litig.*, No. 21-8020 (1st Cir. December 21, 2021).

[5] While there was a brief mention at the December 21st conference about supplemental submissions in connection with the motions *in limine*, the parties agree that no such submissions are warranted.

[6] This assumes that (1) jury selection, preliminary instructions, the jury charge, and deliberations are not included in those three weeks and (2) should the Court elect the April trial date, that religious observance on April 15 and 22 are not included either. The purchasers respectfully suggest that, during *voir dire*, potential jurors be informed that the case may last four weeks (inclusive of those additional aspects of trial) to manage juror expectations and allow jurors to plan for their service accordingly.

so long as the presentation of evidence is not interrupted by excessive, unnecessary objections.[7]

Trial time apportionment. The purchasers ask that the three class plaintiffs and nine certified classes be allotted, collectively, 60% of the total trial time. As the Court recognized, plaintiffs generally have a heavier lift at trial warranting a greater proportion of the trial time being allocated to the plaintiffs' presentation of evidence.[8] Courts recognize that, "in light of the fact that [a] [p]laintiff ha[s] the burden of proof, it might be reasonable to allocate" more hours to the plaintiff than the defendant.[9] Several courts have done so, either in recognition of the plaintiffs' burden at trial,[10] or when there are multiple groups on one side of the "v" and only one on the other.[11] Both justifications apply here.

The purchasers will, by virtue of presenting their case first, be required to introduce the jury to a great number of people, concepts, and timelines—both in opening statements and in

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[7] For example, the defendants are objecting to the relevance of the FDA's CGMP compliance audit of Ranbaxy's Paonta Sahib facility, the FDA's report of its inspection of that facility, and correspondence reflecting Ranbaxy's attempts to explain away the cGMP violations – the very course of conduct that led to the Warning Letters and eventual invocation of the FDA's Application Integrity Policy. The defendants also object to the relevance of the agreement between Parexel, Buc & Beardsley and Ranbaxy. And, as discussed at the conference, they are asserting foundation or authenticity objections to documents that were authenticated, and for which foundations were laid, at deposition.

[8] In fact, one study of civil trials across several case categories found that a plaintiff's presentation averages at least twice as long as a defendant's presentation, with plaintiffs in some categories taking three times as long on average. *See* Dale Anne Sipes, et al., *On Trial: The Length of Civil And Criminal Trials*, Nat'l Ctr. For State Courts 58 (1988). *See also* Engstrom, Nora Freeman, *The Trouble with Trial Time Limits*, 106 GEORGETOWN L.J. 933, 972-73 (2018) ("cutting trial time down the middle is often patently unfair because the plaintiff has the burden of proof and almost necessarily must amass more evidence than the defendant to prevail. … But do plaintiffs really need more time than defendants? The answer, supplied by the NCSC, is a resounding yes."); *see also* The Honorable Nathaniel Gorton, *Time Limits in Civil Jury Trials*, https://civiljuryproject.law.nyu.edu/time-limits-in-civil-jury-trials/ (noting that where counsel cogently presents a request for a time differential, the Court allows it).

[9] *See, e.g., House v. McKean*, 2012 Bankr. LEXIS 3528, at *9-10 (N.D. Cal. Bankr. July 30, 2012).

[10] *Id.* (allocating 57% of the allotted trial time to the plaintiff); Order, *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, No. 19-md-2885 (M.D. Fla., entered Aug. 4, 2021), ECF No. 1852 (allocating 55% of the allotted trial time to plaintiffs); *Navellier v. Sletten*, 262 F.3d 923, 942 (9th Cir. 2001) (initially allocating to plaintiffs 57% of the scheduled trial time, and later extending the plaintiffs' proportion of the hours); Mem & Order at 7, *La. Wholesale Drug Co. Inc. v. Abbott Labs.*, No. 05-cv-340 (N.D. Cal. Nov. 5, 2008), ECF No. 500.

[11] *Cf. Official Comm. of Unsecured Creditors v. Baldwin*, No. 10-cv-800, 2013 U.S. Dist. LEXIS 10339, at *15-18 (W.D. Pa. Jan. 25, 2013) (in a securities case where there was a single plaintiffs group, but two defendants' groups, allocating 12 hours for the plaintiffs' case and 15 hours (56%) to the defendants' case).

the presentation of evidence. The purchasers will need to introduce the jury to each of the three named plaintiffs, as well as explain that they are acting on behalf of nine certified classes, and to explain the differences between direct purchasers and end payor entities. Virtually all of the fact witnesses will be appearing in the purchasers' case, and the jury will need to understand who each of them are and where they fit into the story, a task that will largely fall upon the purchasers. The purchasers will also have to elicit testimony explaining to the jury who other relevant individuals in the documents are: high-level employees at Ranbaxy who helped orchestrate the scheme to mislead the FDA, the individuals at Lachman Consulting who first recommended Ranbaxy fix its cGMP problems in 2004 (but who were specifically rejected by Ranbaxy to fix those problems post-FDA inspection), additional consultants working with Dr. Tetzlaff at Parexel, and individuals employed by the FDA. The purchasers will also need to provide the jury with a preliminary explanation of the complex regulatory framework and related terms and concepts key to the generic drug market, which are not commonly known, but which are at the heart of this case: the Hatch-Waxman Act, Abbreviated New Drug Applications ("ANDAs"), current Good Manufacturing Practices ("cGMP"), first-to-file exclusivity ("FTF"), etc. Simply introducing the three drugs for which the purchasers seek damages (including their approval histories) and the various facilities (Paonta Sahib, Mohali, Toansa, and Dewas) at which Ranbaxy proposed to manufacture those drugs will take time. Finally, the competitive landscape for each of the three drugs, including the multiple would-be competitors for each drug, must be laid out.

These contextual facts, largely incontrovertible but nevertheless important, must be conveyed to the jury. Because they will be first introduced while the purchasers are presenting evidence, the purchasers will need to spend the time—a small amount of time for each, to be sure, but it does accumulate—equipping the jury with the tools it will need to understand the

evidence and find the facts in this case. The defendants, on the other hand, will not need to spend such time on context: by the time the defendants speak to the jury about Ms. Abha Pant, for example, the jury will already know that she worked at Ranbaxy for more than a decade, serving as Head of Regulatory Affairs during the relevant time period. As a result, a 50/50 split of the trial time would leave the purchasers with prejudicially less time than the defendants to try the actually disputed issues in this complex case.

In light of all this, the purchasers submit that the Court should allocate 60% of the total trial time (rounded to the nearest full hour) to the purchasers, and 40% to the defendants. Such an allocation would allow the purchasers to meet their burden to prove the disputed issues in this case, and also allow the purchasers to assume the primary responsibility for providing the jury with the key, but largely undisputed, context for people, concepts, terminology, and events the jury will hear about. This would best serve the Court's goal—which the plaintiffs share—of "secur[ing] the just, speedy, and inexpensive" resolution of this matter.[12]

Dated: January 7, 2022

Respectfully submitted,

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[12] Fed. R. Civ. P. 1.

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CERTIFICATE OF SERVICE

I, Gregory T. Arnold, certify that, on this date, the foregoing was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: January 7, 2022

/s/ Gregory T. Arnold
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